EXHIBIT HH

ETHICON
RESEARCH
FOUNDATION
SOMERVILLE, NEW JERSEY 08876

88 0730

SEP 2 0 1988

Dr. B. Schwartz

cc: Dr. E. C. Barber
Dr. R. L. Kronenthal
Mr. R. Lilenfeld
Dr. D. C. Marshall
Dr. J. R. McDivitt
to
Dr. A. Melveger
Ms. J. Roy
RDCF

TWO YEAR INTERIM REPORT.
PROLENE* POLYPROPYLENE, PVDF,
ETHILON* NYLON AND NOVAFIL SUTURE,
MONOFILAMENT SIZE 5-0: BREAKING STRENGTH
EVALUATION AFTER 2, 5, 7 AND 10 YEARS
SUBCUTANEOUS IMPLANTATION IN THE
BEAGLE DOG

ERF ACCESSION NO.

85-219

PROJECT NO. 16102

PURPOSE

This study was conducted to assess breaking strength and other parameters of PROLENE, PVDF, ETHILON and Novafil suture, monofilament size 5-0, after an *in vivo* subcutaneous residence of 10 years with interim periods of 2, 5 and 7 years.

MATERIALS AND METHODS

Test Materials:

1. PROLENE size 5/0 dyed, Lot # TC 7275
2. PVDF size 5/0 undyed, Lot # 1633223
3. ETHILON size 5/0 dyed, Lot # TA 5061
4. Novafil size 5/0 dyed, Lot # 27635

Experimental Animals:

Twenty-four healthy, mature, female Beagle dogs weighing approximately 6 to 10 kg (Marshall Beagles) were used as the surgical models in this study. The dogs were acclimated in the ETHICON Research Foundation (ERF) vivarium for a minimum of 2 weeks prior to use. Beagles are believed to be of adequate size and temperament for the purpose of this study and a large body of laboratory data is available on this breed for purposes of comparing any responses elicited.

Each dog was identified by a United States Department of Agriculture (USDA) tattoo in the pinna of the ear. In addition, each dog was assigned an ERF number.

ETHICON, INC.

OCT 07 1988

RD-CENTRAL FILE

*Trademark

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The animals utilized in this study were handled and maintained in accordance with the requirements of the Laboratory Animal Welfare Act (PL 89-544), and its amendments (PL 91-579, PL 94-279 and 99-198). Compliance for the above Public Laws will be accomplished by conforming to the standards promulgated in the Guide for the Care and Use of Laboratory Animals, NIH Publication No. 85-23, Revised 1985.

The dogs were housed in the ERF vivarium for a minimum of 10 days postoperatively. The dogs were then transferred to the Scott Research Facility in Washington, NJ. On July 15, 1988 the remaining dogs on study were returned to the ERF vivarium for housing.

Each dog housed at either the Scott Research facility or the ERF vivarium was monitored daily for general condition and care.

Diet consisted of Purina Dog Chow (RALSTON PURINA CO.), and tap water ad libitum except as indicated in surgical aftercare.

Anesthesia:

Each dog was anesthetized with a 2.5% solution of SURITAL (PARKE-DAVIS) administered intravenously. This solution was administered slowly until a sufficient level of anesthesia was obtained for endotracheal intubation. The endotracheal tube was then attached to a VETAFLEX 5 (PITMAN-MOORE) Veterinary Anesthesia Machine. Anesthesia for the remainder of the preparation and surgical procedures was maintained by semi-closed circuit inhalation of METOFANE (PITMAN-MOORE).

RALSTON PURINA CO. - PURINA DOG CHOW
Trademark of Ralston Purina Co.
Checkerboard Square
St. Louis, MO 63164

PARKE-DAVIS - SURITAL Veterinary (thiamylal sodium for injection NF)
Trademark of Parke-Davis
Division of Warner-Lambert Co.
Morris Plains, NJ 07950

PITMAN-MOORE - VETAFLEX 5 Veterinary Anesthesia Machine
METOFANE (methyoxyflurane)
Trademark of Pitman-Moore, Inc.
Washington Crossing, NJ 08560

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Surgical Preparation:

Depilation of the dorsum and lateral thorax was accomplished with an electric animal clipper equipped with a surgical shaving blade. The area was vacummed to remove hair clippings and debris, then scrubbed with NOLVASAN (FORT DODGE), and water. Following scrubbing and drying, the entire area was painted with tincture of Merthiolate 1:1000 (ELI LILLY AND CO.).

Preimplant Suture Inspection:

Prior to implantation, all sutures were 100% inspected by a staff member in the Suture Technology Department using approximately 10X magnification to ensure that no surface damage existed as described in ETHICON's Finished Goods Specification #40, Issue 4, Appendix VII. Personnel conducting the examination were trained to follow proper aseptic technique.

Surgical Procedure:

On each side of the thorax three small incisions, spaced approximately 5 cm apart were made through the skin and cutaneous trunci muscle approximately 3.0 cm from and perpendicular to the midline. Another similar set of incisions was made approximately 15 cm ventral to the initial incisions. A precut flanged segment of a 30 cc polypropylene syringe barrel was positioned subcutaneously in both the dorsal and ventral incisions so as to provide a sterile dam to isolate the subcutaneous implant sites from the cut surface of the skin during implantation.

A bougie (5/16" diameter stainless steel intramedullary bone pin) was inserted into a cannula consisting of a 15 cm piece of 6 mm diameter thin walled disposable plastic tubing. The bougie and cannula were then carefully placed subcutaneously, entering the dorsal skin dam and exiting through the ventral dam. The bougie was carefully withdrawn and six 15 cm long strands of the appropriate suture sample, each bundle secured at both ends with an LC-100 clip, was manipulated through the cannula. The cannula was then withdrawn and discarded, taking care that the strands remained straight in the implant bed. Both ends of each suture bundle were then secured to adjacent subcutaneous tissue with an LC-300 clip. The cutaneous trunci muscle was closed with

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FORT DODGE - NOLVASAN Surgical Scrub
Trademark of Fort Dodge Laboratories, Inc.
Fort Dodge, IA 50501

ELI LILLY AND CO. - TINCTURE No. 99 MERTHIOLATE
THIMEROSAL TINCTURE, USP 1:1000
Trademark of Eli Lilly and Co.
Indianapolis, IN 46285

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PROLENE suture, size 4-0, using a simple continuous suture pattern. The skin incisions were closed with PROXIMATE* skin staples. Similar procedures were performed at the remaining two ipsilateral and three contralateral skin incision sites. Five dogs per time period had sutures implanted in this fashion. Four additional dogs were implanted, as previously described, to be used as replacement animals if required.

The implantation scheme as developed by the Statistics & Computer Applications Department is shown in Table I.

Clinical Procedures:

Blood samples were drawn for analysis before surgery and again approximately one week postoperatively. Thereafter, samples are taken on an annual basis in order to monitor the general health of the animals throughout the study. Analyses were done by the Vet Lab Division of MetPath Inc., Hackensack, NJ 07603. Blood samples obtained from all dogs were subjected to a complete blood count (CBC) which included red cell count, white cell count, hemoglobin, hematocrit, differential and blood cell indices. Samples additionally were drawn for a blood chemistry screening test battery which included A/G ratio, albumin, alkaline phosphatase, bilirubin (direct and total), BUN/creatinine ratio, calcium, chloride, cholesterol, creatinine, gamma glutamyl transpeptidase, globulin, glucose, iron, LDH, magnesium, phosphate, potassium, SGOT, SGPT, sodium, total protein, triglycerides, urea nitrogen, and uric acid.

Pulse rate, body temperature, and respiration rate were taken prior to surgery and daily postoperatively for 7 days following surgery as directed by the veterinary surgeon in charge. Dogs are observed daily throughout the study to determine their health status on the basis of food consumption, excretion and general attitude. Quarterly evaluations of pulse rate, body temperature and respiration rate are conducted.

Dogs are vaccinated annually against canine distemper, hepatitis, leptospirosis, tracheobronchitis and parvovirus infections and every three years for rabies.

Body weights were measured before surgery, every three months thereafter and at the time of scheduled explantation.

Explantation and Sample Inspections:

Dog #2005, which died on February 15, 1985 as an unscheduled death, and the 2 year interim period dog group had suture samples explanted for evaluation. The 2 year interim period dogs were euthanatized by ERF personnel employing an intravenous injection of T-61 Euthanasia Solution (AMERICAN HOECHST CORP.). The thoracic skin was carefully reflected and the suture implants extracted from the subcutaneous tissues without exposing them to physical stress.

American Hoechst Corporation - T-61 Euthanasia Solution
Trademark of American Hoechst Co.
Animal Health Division
Somerville, NJ 08876

*Trademark

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Immediately after explantation one strand of each sample was randomly selected and without being allowed to dry placed in a capped, properly labeled test tube containing sterile deionized water. These samples were submitted for analytical physical and chemical testing according to a protocol developed for this study by the Analytical Chemistry Department (Addendum I). The labeling included dog number and site location. The other 5 strands of each sample were examined for surface damage as described in ETHICON's Finished Goods Specifications #40, Issue 4, Appendix VII. The sutures were then placed in saline-soaked, prelabeled towels, and delivered to Implantation Surgery for tensiometric evaluation. Following tensiometric testing, the suture frements were submitted to the Analytical Chemistry Department.

Tensiometric Evaluation:

Five strands of each test suture recovered from each site were evaluated on an Instron Universal Testing Instrument. Unimplanted samples, stored under existing room conditions, were tested in an identical manner.

The Instron parameters were set as follows:

Instron - Model 1122
Load Cell - Tensiometric Model No. AR2254-1, Serial No. 003
Jaw Faces - Plastic
Jaw Pressure - 50 psi
Gauge Length - 1 inch
Chart Speed - 20 in/min
Crosshead Distraction Rate - 10 in/min

Calculation of average breaking strength, elongation, and modulus were accomplished by Dr. P. Moy of the Suture Technology Department.

Data Handling:

All strip chart recordings of mechanical test data, including peaks and numerical breaking strength values, were grouped and identified by the appropriate United States Department of Agriculture (USDA) tattoo and dog number and filed.

Data Storage:

Upon completion of this study, all relevant raw and finished data, memorandums, and communications will be submitted to the ERF Central File.

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Results:

The Scanning Electron Microscopy Interim Report, from Mr. F. Schiller to Dr. A. J. Melveger, 8/26/87 (Addendum II) presents the SEM surface morphologic data. Tensiometric data are detailed in the report from Dr. P. Moy to Dr. G. Graves, 8/18/88 (Addendum III).

A report on the Infrared Identity and Inherent Viscosity of explanted and unimplanted control suture samples will be issued by the Analytical Chemistry Department.

Reported By: G. M. Graves 9/6/88
G. M. Graves, D.V.M., M.S.
Senior Scientist

Approved By: D. R. Stoloff 9/6/88
D. R. Stoloff, D.V.M., M.S.
Section Manager
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J. D. Paulson, Ph.D.
Director
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ERF Accession No. 85-219

Table I

10 YEAR MONOFILAMENT SUTURE STUDY

RANDOMIZATION PROTOCOL

Implantation Period (Yrs.)		Dog #	Suture Type At Each Site* 1	2	3	4	5	6
2		1993	PROLENE	PVDF	ETHILON	Novafil	PROLENE	Novafil
		1999	PVDF	PROLENE	Novafil	ETHILON	PVDF	PROLENE
	**	2005	ETHILON	Novafil	PROLENE	PVDF	ETHILON	PVDF
		2011	Novafil	ETHILON	PVDF	PROLENE	PROLENE	ETHILON
		2017	PROLENE	PVDF	Novafil	ETHILON	Novafil	PVDF
5		1994	PROLENE	Novafil	ETHILON	PVDF	PROLENE	ETHILON
		2000	Novafil	PROLENE	PVDF	ETHILON	Novafil	PROLENE
		2006	ETHILON	PVDF	PROLENE	Novafil	PVDF	Novafil
		2012	PVDF	ETHILON	Novafil	PROLENE	ETHILON	PVDF
		2018	ETHILON	Novafil	ETHILON	PROLENE	PVDF	Novafil
7		1995	ETHILON	PVDF	PROLENE	Novafil	Novafil	ETHILON
		2001	PVDF	ETHILON	Novafil	PROLENE	PROLENE	Novafil
		2007	PROLENE	Novafil	ETHILON	PVDF	PVDF	PROLENE
		2013	Novafil	PROLENE	PVDF	ETHILON	ETHILON	PVDF
		2019	Novafil	PROLENE	PROLENE	PVDF	ETHILON	ETHILON
10		1996	Novafil	PVDF	ETHILON	PROLENE	PROLENE	Novafil
		2002	PVDF	Novafil	PROLENE	ETHILON	PVDF	PROLENE
		2008	ETHILON	PROLENE	Novafil	PVDF	ETHILON	PVDF
		2014	PROLENE	ETHILON	PVDF	Novafil	Novafil	ETHILON
		2020	PVDF	ETHILON	PVDF	Novafil	Novafil	PROLENE
Replacements		1997	PROLENE	PVDF	ETHILON	Novafil	PROLENE	Novafil
		2003	Novafil	ETHILON	PVDF	PROLENE	PVDF	PROLENE
	**	2009	PVDF	Novafil	PROLENE	ETHILON	ETHILON	PVDF
		2015	ETHILON	PROLENE	Novafil	PVDF	Novafil	ETHILON

* Site 1 = Left Cranial
Site 2 = Left Middle
Site 3 = Left Caudal
Site 4 = Right Cranial
Site 5 = Right Middle
Site 6 = Right Caudal

** Dog #2005, which died on February 15, 1985 as an unscheduled death, was replaced with dog #2009.

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ADDENDUM I

ETHICON, INC.
a Johnson & Johnson company
SOMERVILLE · NEW JERSEY · 08876-0151

June 3, 1985

Ms. P. A. Britnell

cc: Mr. D. F. Burkley
Dr. N. Cholvin
Dr. T. Davidson
Dr. A. Fetter
Dr. R. L. Kronenthal
Mr. R. Lilenfeld
Ms. B. Matlaga
Dr. A. J. Melveger
Dr. R. F. Morrissey
Dr. P. Moy
Mr. F. Schiller
RDCF

ANALYTICAL TESTING OF LONG-TERM NONABSORBABLE SUTURE IN-VIVO STUDY

The following analyses will be performed on 5/0 PROLENE* polypropylene suture, PVDF, ETHILON* nylon suture and Novafil material to be implanted in the ten-year dog in-vivo study:

1. SEM
2. Infrared Microscopy
3. Infrared (identity)
4. Inherent Viscosity
5. Gel Permeation Chromatography

The current protocol calls for five explant time periods of 1, 2, 5, 7 and 10 years. Five dogs will be used per explant time period, and each dog will have six implant sites with each site containing six sutures (6 inches) of one type of material. The four suture materials have been randomized among the thirty sites of each explant period (six sites per dog times five dogs) so that 7 or 8 sites will exist for each material per explant period.

*Trademark

The sample requirements to do the analytical testing will be as follows:

ANALYTICAL TECHNIQUE	SAMPLES PER EXPLANT PERIOD	REMARKS
SEM IR MICROSCOPY	One strand per site per dog	A strand per site will be selected at random, placed in a water solution and transferred to Analytical Chemistry. Dog and site identity indicated.
	Total 7 or 8 strands per material	
INFRARED IDENTITY INHERENT VISCOSITY GEL PERMEATION CHROMATOGRAPHY	After tensile pulls the remaining fragments from five strands per site per dog	Dog and site identity of fragments to be indicated.
	Total - 35 or 40 strand fragments per material	

The strands for SEM and infrared microscopy will be selected at random among the six strands per site. Arrangements will be made among Ms. Matlaga, and Messrs. Schiller and Burkley for sample treatment to remove protein and for sample examination. Mr. E. Muse will receive the tensile strength tested fragments of the remaining five fibers of each material per site.

J. McDivitt, Ph.D.

mr

1611N/3

ADDENDUM II

ETHICON, INC.
a Johnson & Johnson company
SOMERVILLE · NEW JERSEY · 08876-0151

August 26, 1987

Dr. A. J. Melveger

cc: Ms. K. Braun
Dr. G. Graves
Dr. A. Levy
Mr. R. Lilenfeld
Dr. J. McDivitt
Dr. R. Morrissey
Dr. D. Sheffield
Dr. S. Trenka-Benthin
RDCF

TEN YEAR IN-VIVO SUTURE STUDY
SCANNING ELECTRON MICROSCOPY
INTERIM REPORT

To further understand the long-term effects on nonabsorbable sutures, 5/0 PROLENE* polypropylene suture, PVDF, ETHILON* nylon suture and Novafil were implanted in dogs for up to ten years. The surface morphology of sutures explanted from dogs after several months (unscheduled death), one year and two years have been evaluated by SEM.

The results are summarized in the attached table. Seven or eight sutures were evaluated of each product at each time period according to the established protocol. With the exception of one suture after two years in-vivo, PROLENE displayed no discernible cracking.

Likewise, only one PVDF suture after two years in-vivo showed signs of possible cracking. However, longitudinal score marks and surface detents were evident on several samples.

Four of seven Novafil sutures showed surface cracking or were suspected of cracking after one year in-vivo. After two years in dogs, only two of seven samples revealed cracking.

In contrast, ETHILON produced a cracked surface in virtually all samples at all time periods including the unscheduled specimens.

The next scheduled explants are due in 1990.

F. Schiller/ajm

F. D. Schiller

rmw
Attachment
1949N/28

*Trademark

TABLE 1

Period	Product	SEM Observations	SR #	Acc. #	Dog #	Site
Unsched.	Prolene	No cracking	23577	-	2005	3
1 year	Prolene	No cracking	24195	85-226	1992	1
1 year	Prolene	No cracking	24195	85-226	1992	5
1 year	Prolene	No cracking	24195	85-226	1998	2
1 year	Prolene	No cracking	24195	85-226	1998	6
1 year	Prolene	No cracking; some transverse folds	24195	85-226	2004	3
1 year	Prolene	No cracking	24195	85-226	2010	4
1 year	Prolene	No cracking	24195	85-226	2010	5
1 year	Prolene	No cracking	24195	85-226	2016	1
2 year	Prolene	No cracking	25649	85-219	1993	1
2 year	Prolene	No cracking	25649	85-219	1993	5
2 year	Prolene	No cracking	25679	85-219	1999	2
2 year	Prolene	No cracking	25679	85-219	1999	6
2 year	Prolene	No cracking	25712	85-219	2009	3
2 year	Prolene	No cracking	25742	85-219	2011	4
2 year	Prolene	Cracking	25742	85-219	2011	5
2 year	Prolene	No cracking	25825	85-219	2017	1
Unsched.	PVDF	No cracking	23577	-	2005	4
Unsched.	PVDF	No cracking	23577	-	2005	6
1 year	PVDF	No cracking; some surface detents	24195	85-226	1992	2
1 year	PVDF	No cracking	24195	85-226	1998	1
1 year	PVDF	No cracking	24195	85-226	1998	5
1 year	PVDF	No cracking	24195	85-226	2004	4
1 year	PVDF	No cracking	24195	85-226	2004	6
1 year	PVDF	No cracking	24195	85-226	2010	3
1 year	PVDF	No cracking; longitudinal score marks	24195	85-226	2016	2
1 year	PVDF	No cracking	24195	85-226	2016	6
2 year	PVDF	No cracking	25649	85-219	1993	2
2 year	PVDF	No cracking; longitudinal score marks	25679	85-219	1999	1
2 year	PVDF	Possible cracking	25679	85-219	1999	5
2 year	PVDF	No cracking	25712	85-219	2009	1
2 year	PVDF	No cracking	25712	85-219	2009	6
2 year	PVDF	No cracking; longitudinal score marks	25742	85-219	2011	3
2 year	PVDF	No cracking	25825	85-219	2017	2
2 year	PVDF	No cracking	25825	85-219	2017	6

TABLE 2

Period	Product	SEM Observations	SR #	Acc. #	Dog #	Site
Unsched.	Ethilon	Cracking	23577	-	2005	1
Unsched.	Ethilon	Cracking	23577	-	2005	5
1 year	Ethilon	Cracking; longitudinal score marks	24195	85-226	1992	3
1 year	Ethilon	Cracking	24195	85-226	1998	4
1 year	Ethilon	Cracking	24195	85-226	2004	1
1 year	Ethilon	Possible cracking; heavily gouged	24195	85-226	2004	5
1 year	Ethilon	Heavy cracking	24195	85-226	2010	2
1 year	Ethilon	Cracking	24195	85-226	2010	6
1 year	Ethilon	Cracking	24195	85-226	2016	4
2 year	Ethilon	Cracking; deep indentations	25649	85-219	1993	3
2 year	Ethilon	Heavily abraded	25679	85-219	1999	4
2 year	Ethilon	No cracking	25712	85-219	2009	4
2 year	Ethilon	Cracking	25712	85-219	2009	5
2 year	Ethilon	Cracking	25742	85-219	2011	2
2 year	Ethilon	Cracking	25742	85-219	2011	6
2 year	Ethilon	Some cracking	25825	85-219	2017	4
Unsched.	Novafil	No cracking	23577	-	2005	2
1 year	Novafil	Possible cracking	24195	85-226	1992	4
1 year	Novafil	No cracking	24195	85-226	1992	6
1 year	Novafil	No cracking; longitudinal score marks	24195	85-226	1998	3
1 year	Novafil	Possible cracking	24195	85-226	2004	2
1 year	Novafil	No cracking	24195	85-226	2010	1
1 year	Novafil	Cracking	24195	85-226	2016	3
1 year	Novafil	Slight cracking	24195	85-226	2016	5
2 year	Novafil	No cracking	25649	85-219	1993	4
2 year	Novafil	No cracking	25649	85-219	1993	6
2 year	Novafil	No cracking	25679	85-219	1999	3
2 year	Novafil	Slight cracking	25712	85-219	2009	2
2 year	Novafil	Cracking	25742	85-219	2011	1
2 year	Novafil	No cracking	25825	85-219	2017	3
2 year	Novafil	No cracking	25825	85-219	2017	5

ADDENDUM III

ETHICON, INC.
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August 18, 1988

Dr. Glenn Graves

cc: Dr. E. Barber
Mr. D. Lennard
Mr. R. Lilenfeld
Dr. B. Schwartz
Dr. A. Skinner

10 YEAR PROLENE BSR STUDY

The physical properties of explanted and control samples of size 5/0 ETHILON, NOVAFIL, PROLENE and PVDF sutures at the two year mark of the ten year BSR study have been compiled. The results are given in Table 1. Findings are summarized as follows. Implanted ETHILON sutures show a decrease in breaking strength of 14% at the one year period when compared to the unimplanted controls. The suture maintains this strength level into the two year period. Novafil sutures show a corresponding decrease of 4% in breaking strength through the one and two year periods. The breaking strength of PROLENE and PVDF sutures show no significant changes through the two time periods. Elongation and modulus values for all the test samples remain within the statistical variation of the control materials.

Conditions used for the data analysis were 1 in./min. crosshead speed (XH) and 10 in./min. chart speed (CS) for the one year PROLENE controls and explants, 1 in./min. XH and 5 in./min. CS for the two year PROLENE samples, and 5 in./min. XH and 20 in./min. CS for all other samples. The conditions were based on the supplied charts and expected value ranges for the test materials.

P. Moy, Ph.D.

sac/0032c/21

Table 1

One and Two Year Data Summary - 10 Year Prolene Study

	Sample I.D.	Breaking Strength (lb)	(std dev)	Elong (%)	(std dev)
1 year	Ethilon-Unimplanted	2.13	0.08	26.87	1.61
	Ethilon-1992-site3	1.85	0.08	34.37	1.56
	Ethilon-1998-site4	1.86	0.07	31.56	3.01
	Ethilon-2004-site4	1.88	0.06	29.38	2.57
	Ethilon-2004-site1	1.39	0.27	20.62	5.88
	Ethilon-2010-site6	1.87	0.08	34.37	1.11
	Ethilon-2010-site2	1.72	0.03	28.44	1.31
	Ethilon-2016-site4	1.78	0.09	27.19	1.78
2 year	Ethilon-Unimplanted	2.04	0.07	27.49	2.11
	Ethilon-1993-site3	1.80	0.07	25.94	1.78
	Ethilon-1999-site4	1.85	0.05	27.18	0.85
	Ethilon-2009-site5	1.65	0.09	20.93	1.39
	Ethilon-2009-site4	1.76	0.02	25.00	1.91
	Ethilon-2011-site6	1.67	0.05	22.81	0.86
	Ethilon-2011-site2	1.73	0.05	24.69	2.04
	Ethilon-2017-site4	1.80	0.05	25.94	1.78
1 year	Novafil-Unimplanted	1.76	0.01	37.34	1.87
	Novafil-1992-site6	1.69	0.01	41.25	2.37
	Novafil-1992-site4	1.65	0.01	42.81	3.76
	Novafil-1998-site3	1.69	0.01	42.19	1.28
	Novafil-2004-site2	1.66	0.01	37.50	1.56
	Novafil-2016-site5	1.68	0.01	40.62	1.11
	Novafil-2016-site3	1.70	0.00	40.31	4.19
2 year	Novafil-Unimplanted	1.69	0.03	36.40	1.48
	Novafil-1993-site6	1.64	0.06	31.87	1.78
	Novafil-1993-site4	1.68	0.06	30.94	1.30
	Novafil-1999-site3	1.64	0.01	32.19	0.85
	Novafil-2009-site2	1.63	0.01	32.19	2.09
	Novafil-2011-site1	1.61	0.01	33.75	0.85
	Novafil-2017-site5	1.60	0.00	34.06	1.31
	Novafil-2017-site3	1.66	0.02	32.19	1.39
1 year	Prolene-Unimplanted	1.68	0.04	37.06	2.65
	Prolene-1992-site1	1.66	0.01	40.99	2.37
	Prolene-1998-site6	1.65	0.03	42.65	1.79
	Prolene-1998-site2	1.54	0.07	39.12	9.52
	Prolene-2004-site6	1.63	0.03	37.19	2.13
	Prolene-2010-site5	1.20	0.24	23.87	13.07
	Prolene-2010-site4	1.58	0.03	37.49	4.24
	Prolene-2016-site1	1.63	0.03	37.37	1.49
2 year	Prolene-Unimplanted	1.60	0.03	36.37	3.25
	Prolene-1993-site5	1.64	0.01	33.25	2.44
	Prolene-1993-site1	1.64	0.02	30.00	3.95
	Prolene-1999-site6	1.61	0.04	32.25	4.95
	Prolene-1999-site2	1.65	0.04	33.75	2.34
	Prolene-2009-site3	1.66	0.01	31.50	2.24

	Prolene-2011-site5	1.65	0.01	32.75	2.98
	Prolene-2011-site4	1.69	0.05	36.50	2.71
	Prolene-2017-site1	1.62	0.03	29.37	4.14
1 year	PVDF-Unimplanted	2.17	0.06	34.06	2.30
	PVDF-1992-site2	2.14	0.01	37.80	1.59
	PVDF-1998-site5	2.11	0.03	45.31	2.21
	PVDF-1998-site1	2.06	0.07	42.17	5.52
	PVDF-2004-site5	2.13	0.02	41.87	4.74
	PVDF-2004-site3	2.09	0.06	41.40	6.05
	PVDF-2010-site3	2.14	0.02	38.53	3.27
	PVDF-2016-site6	2.15	0.05	40.31	2.79
	PVDF-2016-site2	2.11	0.08	38.75	3.73
2 year	PVDF-Unimplanted	2.13	0.05	33.85	1.56
	PVDF-1993-site2	2.15	0.06	39.69	5.37
	PVDF-1999-site5	2.13	0.06	36.25	1.30
	PVDF-1999-site1	2.13	0.03	35.94	1.10
	PVDF-2009-site6	2.22	0.03	35.63	2.79
	PVDF-2009-site1	2.17	0.03	34.06	0.69
	PVDF-2011-site3	2.22	0.03	40.94	2.04
	PVDF-2017-site6	2.15	0.07	41.01	5.89
	PVDF-2017-site2	2.09	0.11	36.87	1.78

Modulus (psi)	(std dev)	Sample I.D.
544000.00	149000.00	Ethilon-Unimplanted
349000.00	31000.00	Ethilon-1992-site3
330000.00	15000.00	Ethilon-1998-site4
375000.00	22500.00	Ethilon-2004-site4
360000.00	28200.00	Ethilon-2004-site1
319000.00	11000.00	Ethilon-2010-site6
359000.00	18900.00	Ethilon-2010-site2
370000.00	23800.00	Ethilon-2016-site4
565000.00	80800.00	Ethilon-Unimplanted
402000.00	31400.00	Ethilon-1993-site3
515000.00	58900.00	Ethilon-1999-site4
527000.00	92200.00	Ethilon-2009-site5
478000.00	89400.00	Ethilon-2009-site4
473000.00	60400.00	Ethilon-2011-site6
378000.00	27500.00	Ethilon-2011-site2
368000.00	23800.00	Ethilon-2017-site4
369000.00	42400.00	Novafil-Unimplanted
340000.00	30500.00	Novafil-1992-site6
347000.00	67600.00	Novafil-1992-site4
324000.00	16100.00	Novafil-1998-site3
327000.00	26500.00	Novafil-2004-site2
277000.00	38600.00	Novafil-2016-site5
269000.00	16800.00	Novafil-2016-site3
282000.00	46200.00	Novafil-Unimplanted
273000.00	41300.00	Novafil-1993-site6
272000.00	35800.00	Novafil-1993-site4
399000.00	69300.00	Novafil-1999-site3
299000.00	30900.00	Novafil-2009-site2
308000.00	35100.00	Novafil-2011-site1
287000.00	38100.00	Novafil-2017-site5
267000.00	24900.00	Novafil-2017-site3
721000.00	210000.00	Prolene-Unimplanted
532000.00	56600.00	Prolene-1992-site1
788000.00	147000.00	Prolene-1998-site6
500000.00	11300.00	Prolene-1998-site2
678000.00	41500.00	Prolene-2004-site6
833000.00	187000.00	Prolene-2010-site5
804000.00	122000.00	Prolene-2010-site4
492000.00	19400.00	Prolene-2016-site1
569000.00	49100.00	Prolene-Unimplanted
574000.00	79400.00	Prolene-1993-site5
653000.00	83900.00	Prolene-1993-site1
755000.00	96900.00	Prolene-1999-site6
711000.00	126000.00	Prolene-1999-site2
875000.00	93900.00	Prolene-2009-site3

706000.00	48200.00	Prolene-2011-site5
574000.00	54000.00	Prolene-2011-site4
564000.00	57500.00	Prolene-2017-site1
330000.00	34400.00	PVDF-Unimplanted
318000.00	22100.00	PVDF-1992-site2
326000.00	37600.00	PVDF-1998-site5
292000.00	6000.00	PVDF-1998-site1
316000.00	27100.00	PVDF-2004-site5
311000.00	29700.00	PVDF-2004-site3
331000.00	75900.00	PVDF-2010-site3
285000.00	23800.00	PVDF-2016-site6
269000.00	11900.00	PVDF-2016-site2
319000.00	30100.00	PVDF-Unimplanted
468000.00	73800.00	PVDF-1993-site2
338000.00	35700.00	PVDF-1999-site5
442000.00	103000.00	PVDF-1999-site1
531000.00	79200.00	PVDF-2009-site6
364000.00	18300.00	PVDF-2009-site1
383000.00	16000.00	PVDF-2011-site3
301000.00	25800.00	PVDF-2017-site6
305000.00	16500.00	PVDF-2017-site2

Data Analysis Conditions

XH = 1 in/min CS = 10 in/min - 1 Year Prolene Samples
XH = 1 in/min CS = 5 in/min - 2 Year Prolene Samples
XH = 5 in/min CS = 20 in/min - All Other Samples

Diameter = 5.5 mil for Modulus Calculations

PLEASE USE YELLOW HIGHLIGHTER PEN TO HIGHLIGHT WORDS ERF Acc. No. 85-219

1) ADDITIONAL SAMPLE DESCRIPTION
(include only if not in title)
Form:

Mesh	Mono
Staple	Braid
Clip	Dyed
Absorbable	Undyed
Adhesive	Coating_____
Film	Size_____
Coupler	Other_____
Non-absorbable	

2) ADDITIONAL STUDY DESCRIPTION
Study Type:

Tissue reaction	Demonstration
Absorption	Sales School
Breaking strength	Laser
Function	GLP
Developmental	Ex vivo
Product Service Review	In vitro
Product Inquiry Affiliate	Dept. objective
Veterinary inquiry	Training study
Pilot	Competitive test
Cancer	Comparative
Allergen	Patency
Intracutcut Irritat	Stability
Mutagen	Hinge strength
Pyrogen	Tensiometry
Acute tox	Photomicrography
Gross TR	
Other_____	

Implant Site:

SQ	Stomach
IM	Genital tract
Eye	Lung
Vascular	Skin
IP	Small intestine
IV	Spleen
Intradermal	Colon
Dura	Bone
Urinary bladder	Other_____

Implant period-days: List

2633A/cal

Test system:

Rat	Cell culture
Mouse	Guinea pig
Rabbit	Pig
Dog	Goat
Human	Other_____

Photography:

Gross photo	Video
Micro photo	SEM photo
TEM photo	Other_____

3) ADDITIONAL HISTOLOGY DESCRIPTION:
Embed:

GMA	Ground section
Frozen section	Other_____

Special Stains:

ORO	Iron
Silver	Calcium
Trichrome	Geimsa
PAS	Gram
PTAH	Immunohistochem
VG	Other_____

Slides, no slides, histopath report

4) SURGICAL DESCRIPTION:

Anastomosis vascular	Keratotomy
Anastomosis-_____	Laparotomy
Colotomy	Lobectomy
Craniotomy	Splenectomy
Cystotomy	Thoracotomy
Gastrotomy	Ligation
Ovariohysterectomy	Other_____

5) MISCELLANEOUS:

Biochem analysis	Other Infared ident.
Clinical pathology	Other Inherent viscosity
Radiography	Other Gel permeation Chromatography
Biomechanics test	